

Registration of Facilities Questions

02N-0276

REF 2



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Food and Drug Administration

Center for Food Safety and Applied Nutrition

**Instructions: Please print one question per sheet.
Include your name and affiliation.**

QUESTIONS FOR PANELISTS

Name: JOHN A. LEGER

Affiliation: AMERICAN TRUCKING ASSOCIATIONS

① Will there be any PARTICULAR Requirements or
different Requirements for motor carriers?

② Will there be a threat assessment or QUALIFICATION
PROCESS DONE ON THE REGISTRATIONS? IF SO,
what will that ENTAIL?



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QUESTIONS FOR PANELISTS

Name: *Marcia Donner*

Affiliation: *Brazilian Embassy*

On registration of foreign food facilities

(a) are documents required?

(b) are there costs?

*(c) products entering US under "draw-back"
require registration?*

(d) is there a deadline / timeframe for

*retention of products imported from
non-registered facilities?*



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QUESTIONS FOR PANELISTS

Name:

William McVicker

Affiliation:

Recall Analytics Inc.

*IS ALL THIS REGISTRATION
INFORMATION AVAILABLE
THROUGH FREEDOM
OF INFORMATION?*



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QUESTIONS FOR PANELISTS

Name: PHILIP CORRIGAN

Affiliation: AUSTRALIAN DEPARTMENT OF
AGRICULTURE (FEDERAL)

If all processing plants in a foreign
country are registered with the Competent
Authority (government) of the foreign country —
and the Foreign Government ^{formally} provides this list
to ~~with~~ the FDA — does each individual
plant in that country have to register
with the FDA. ?

Thank you

Philip Corrigan



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QUESTIONS FOR PANELISTS

Name: Stephen Payne

Affiliation: Pet Food Institute

Pet/animal shelters are exempt from
the rule - does that exemption apply to
veterinary clinics that sell food to
pet owners and use food, during treatment
or boarding, for example?



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QUESTIONS FOR PANELISTS

Name:

Patty Rochette

Affiliation:

National Food Processors Assn

If a foreign establishment ships to

several U.S. Clients or "Agents" must

all be identified? Do modification

to Customer lists require amended registration?



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QUESTIONS FOR PANELISTS

Name: CAROLINE FEITEL

Affiliation: NETHERLANDS EMBASSY

Does the registration number have to be
listed on packaging? (Foreign establishments)

Who does a foreign company list as its agent,
if they deliver directly to retail facility?



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QUESTIONS FOR PANELISTS

Name: *Ed Steele*

Affiliation: *AAC Consulting Group.*

What is the role of the U.S. agent?



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QUESTIONS FOR PANELISTS

Name: SAM GILSTON

Affiliation: WASH TARIFF & TRADE LETTER

HOW DID THE BIOTERRORISM ACT

AMEND FDA DEFINITION OF FOOD?



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QUESTIONS FOR PANELISTS

Name: JOHN LUEDKE

Affiliation: COVINGTON & BURUNG

How should Firms whose only product
is not one of the defined categories
report their products?

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QUESTIONS FOR PANELISTS

Name: Robert Proelli, Esq. rproelli@itmassociates.com

Affiliation: ITM

For Dr. Russo

Web-based Electronic Forms technology based upon PDF Formats

is being used at EPA, Department of Commerce,

and the USDA as well as FoodTrace, Inc. which

uses this technology to meet similar registration

requirements under the Organic Food Production Act.

Do you plan to use existing commercially available

e-forms technology or will you create your own

technology = "in-house"?



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QUESTIONS FOR PANELISTS

Name: Ken Klippen

Affiliation: United Egg Producers

For Dr. Frasher:

Some of my members have off-sight processing
of eggs into liquid or dried product. Depending
on market conditions, they ~~may~~ choose to
sell eggs in the shell-form. In the ~~processing~~ ^{processing}
into liquid, they are regulated by USDA.
If sold in shell, they are regulated by
FDA. Must they register?



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QUESTIONS FOR PANELISTS

Name: Sarah Key

Affiliation: Keller and Heckman LLP

Are facilities/firms that manufacture food
contact/packaging materials subject to the
registration requirements?



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QUESTIONS FOR PANELISTS

Name: REGINA HILDWINE

Affiliation: NATIONAL FOOD PROCESSORS ASSN.

RE: REGISTRATION

Apparently the proposed rule (and the statute, I believe)

requires the registrant to register all their "trade

names." How does the proposal define these

"trade names?"



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QUESTIONS FOR PANELISTS

Name: JEFFREY LEWIS

Affiliation: PRINCE GEORGE'S COUNTY HEALTH DEPT.
MARYLAND

How are the operators being informed
of these requirements? I have some
facilities that didn't know that had
to have a license!



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QUESTIONS FOR PANELISTS

Name: Patrick Donoho

Affiliation: Intl. Bottle Water Assn

~~Will holds for failure to register~~

Will holds for failure to register and failure to give prior notice include specific information on why the hold occurred and a method for removal of the hold?

If a threat to imports occur and product is held, will those be ~~not~~ handled differently?



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QUESTIONS FOR PANELISTS

Name: M.H. Auerbach

Affiliation: Danisco USA Inc

Can the FDA refuse to accept a
registration from a particular
facility?



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QUESTIONS FOR PANELISTS

Name: Gabriele Ludwig

Affiliation: Schramm, Williams + Associates

Packing of fresh produce in the field?

Example: cantaloupes, etc. are, proper packed in
field in consumer ready packages

field - then shipped out or moved
to storage (on farm) before shipment.

~~When~~ register ~~in~~ when need to register?



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QUESTIONS FOR PANELISTS

Name: Fletcher HALL

Affiliation: American Trucking Assn

A ~~CARRIER~~ picks up a load,
from a facility that represents
it is registered and the
carrier stops at the border
and finds out the company
doing the shipping is NOT
registered. Who is
responsible? What happens?



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QUESTIONS FOR PANELISTS

Name: John Conley

Affiliation: NTTC

Is food in a rail car
or truck trailer considered
under "storage?"

Do mfrs of ~~food~~ trailers
that transport food need
to register?



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QUESTIONS FOR PANELISTS

Name:

THOMAS HERR

Affiliation:

EMBASSY

- Who / whose be will do the test ?

- How long does it need ?

- Time to the Recall ?

- Facility will be Black listed after the first time ?



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QUESTIONS FOR PANELISTS

Name: Clay Detlefsen

Affiliation: Intl Dairy Foods Ass'n

Has FDA considered the registration
of facilities (buildings) that may or
may not be contiguous to a main
processing building? For example can
auxiliary storage locations, R+D facilities,
etc., all be included in a single
registration or will each building
need to be registered.